

REMARKS**Status of the Claims**

Claims 1-20 are pending. Because claims 14 and 16 have been withdrawn from consideration, only claims 1-13, 15, and 17-20 are at issue.

Election of Species Requirement

Applicants confirm the election of the claims of Group II (claims 1-13, 15, and 17-20 directed to escitalopram) for further prosecution in this application.

Rejection under 35 U.S.C. §103(a)

Claims 1-13, 15, and 17-20 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,912,256 (Koch). The Examiner contends that Koch teaches a wet granulated composition comprising a polymer, a binder and a drug.

Applicants respectfully traverse this rejection, and request reconsideration.

Claims 1-13, 15, and 17-20 are directed to a melt granulated composition. Koch, however, does not disclose or suggest a melt granulated composition. Koch states that the “[t]ablets [described therein] are prepared by direct compression, by wet granulation, or by dry granulation.” Koch, col. 24, ll. 8-9. These techniques, however, are different from melt granulation.

Melt granulation generally involves the use of solids having a relatively low softening or melting range heated to a temperature at or near their melting range to act as a binder or a granulating medium. *See* page 2, lines 15-23, of the specification. In contrast, direct compression

involves directly compressing powder blends of the active ingredient and suitable excipients which will flow uniformly into a die cavity and form into a firm compact. *See Pharmaceutical Dosage Forms: Tablets* (Volume 1) (1980) (Edited by H. Lieberman and L. Lachman), p. 147 (copies of the pertinent excerpts are attached). Wet granulation involves “moistening [a] mixture of active ingredient and diluent with [a] granulating liquid comprising the binder in solution in water, alcohol, or mixture of these two, or any other acceptable liquid to moisten and bind the powders together by causing the particles to adhere to each other.” *Id.* at p. 116; *see also* page 2, lines 5-8, of the specification. Dry granulation refers to the granulation of a powder mixture by compression and without the use of heat and solvent. *Id.* at p. 173.

Accordingly, a person of ordinary skill in the art would not have had any motivation based on Koch to prepare a melt granulated composition as presently claimed.

For the foregoing reasons, Koch fails to render obvious claims 1-13, 15 and 17-20, and applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 101

Claims 1-6, 10-13, 19 and 20 have been rejected under 35 U.S.C. §101 for claiming the same invention as in claims 1-7, 9-17, 21 and 23 of U.S. Patent No. 5,403,593 (Royce).

Applicants respectfully traverse this rejection, and request reconsideration.

Royce claims a composition which comprises, *inter alia*, a glyceryl ester of a fatty acid. See independent claims 1, 16 and 21 of Royce. The presently pending claims do not recite such a glyceryl ester. Accordingly, the present application does not claim the same invention as that claimed in Royce, and applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above arguments, the pending claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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